Although the objective assessment of lung function is an important component of care in evaluating the pediatric patient, it offers unique challenges. Pulmonary function test reliability is determined by published standards and guidelines. The ability to meet or exceed these guidelines, however, is a function of patient performance. The National Lung Health Study has evaluated the ability of an adult population to meet the American Thoracic Society (ATS) spirometry recommendations. But studies have not evaluated the ability of children across a wide age range to meet ATS and AARC Clinical Practice Guidelines (CPG) for spirometry (FVC), lung volumes (TGV), and airway mechanics (Raw) measurements.

Objective pulmonary function testing data to establish bronchoreactivity, as well as the responses to treatment changes, have often been perceived as too complicated for children to accomplish. Most drugs have not been adequately tested in pediatrics due to the challenges associated with conducting clinical trials in this patient population. Insufficient testing frequently results in product labeling that fails to provide instructions for safe and effective use in pediatric patients. Many asthma medications have not been evaluated in infants and young children, although this is changing with increased requests by the FDA to evaluate drugs in this population.

The use of serial testing of some pulmonary function tests yields clinically useful data when evaluating patients from the premature infant to the elderly adult. Namely, studies of airway mechanics, especially airway resistance (Raw) measurements, have suggested that disease is present and responsive to therapy across all age ranges.

The recommended use of objective assessment appears in national guidelines. For example, spirometry is recommended by the National Asthma Education and Prevention Program (NAEPP) for the initial evaluation of the patient with asthma, during therapeutic interventions, and annually thereafter, with a primary goal to maintain normal lung function.

What age to begin?

The answer to this question will vary based on the test and its reliability in a specific age group. For this article, infant lung function testing will not be discussed. Over the past several years, an increasing amount of information has been published related to pulmonary function testing in the very young child (ages 2 to 5). In a review, Janet Stocks states that we are currently witnessing something of a revolution in the field of respiratory function testing during early childhood, both with respect to the number of techniques available and the applications to which they are being put. She goes on to say that there is an urgent need for international, collaborative efforts to develop more objective, standardized methods of assessment (including improved, properly validated equipment and software) and reliable reference data for this age group. By 6 years of age most children, with coaching, can reliably perform spirometry (FVC). Multiple other tests that assess lung function, including lung volumes (TGV), diffusing capacity (DLCO), airway mechanics (Raw) measurements, and cardiopulmonary exercise, are also commonly performed in this age group.

What can they do?

In the Michigan State University Pediatric Pulmonary Laboratory, we have examined which lung function tests children can reliably perform and at what level of quality for the diagnosis and monitoring of pediatric asthma. A retrospective analysis was performed on 71 current asthmatic patients, ages 4-18, in the pediatric pulmonary practice.
Each child had performed pre- and post-aerosol bronchodilator forced vital capacity (FVC), thoracic gas volume (TGV), and airway resistance (Raw) using the MedGraphics 1085 plethysmograph.

In this evaluation, two respiratory therapists performed the testing. Both were credentialed in pulmonary function testing and evaluated for competency in pediatric testing. The performance standards in the laboratory followed the AARC clinical practice guidelines, as well as those procedures described in the 1998 ATS Management and Procedure Manual for Pulmonary Function Laboratories, Chapters 6, 8, and 9. Each trial was evaluated for conformity with ATS acceptability and reproducibility criteria for spirometry, lung volumes, and airway resistance. A 1-8 progressive quality score (QS) was assigned to each pre- and post-FVC, TGV, and Raw result. The mean quality scores were as follows:

- Raw: 7.49
- Spirometry: 7.01
- Lung volumes: 5.14
- Age: 10

Airway measurements achieved the highest quality scores. The spirometry quality scores were similar to other published data for this age group. Lung volumes were the most difficult measurements to obtain in this pediatric population. Interestingly, it appears that lower quality scores do not correlate with any particular age. Most of the very young children performed all of the PF tests, while some adolescents were unable to do many of the tests. Airway resistance measurements, particularly specific conductance, provides useful data on which to make therapeutic decisions, especially when archived and used for longitudinal patient care decision-making. This is of particular importance in the pediatric population with asthma.

Eigen, et al, evaluated spirometric lung function in normal children ages 3 to 6 years. Spirometric measurements were obtained at nursery and daycare centers by experienced pediatric pulmonary function technicians. In this study, 82.6% (214) were able to perform technically acceptable and reproducible maneuvers during a testing session limited to 15 minutes. Enright, et al, demonstrated that in 4,000 public school students 9-18 years, 95% of the tests met adult-based ATS standards.

Klug, et al, assessed the within-observer and between-observer variability of lung function measurements in children aged 2-6 years. Two individuals independently tested 22 asthmatic children according to a predefined protocol. Each individual observer obtained duplicate measurements of respiratory resistance by the interrupter technique, respiratory resistance and reactance at 5 Hz by the impulse oscillation technique, and the specific airway resistance by whole body plethysmography. The within subject standard deviation was not significantly different between the two observers. The authors concluded that specific airway resistance, impulse oscillation technique, and respiratory resistance assessed by the interrupter technique measurements in young children are subject to influence by the observer. The random variability between observers appeared to be particularly great for respiratory resistance assessed by the interrupter technique.

Nielsen, et al, studied the feasibility, sensitivity, specificity, predictive value, and repeatability of cold, dry air challenge as a diagnostic test for asthma in young children 2 to 5 years of age. The primary outcome measurement was specific airway resistance (sRaw) by whole body plethysmography. Resistance was also measured by the interrupter technique and by the impulse oscillation technique. At baseline, lung function measures differed significantly between asthmatics and healthy control subjects. Specific resistance had the highest sensitivity (68%). Specificity ranged from 93-100%. The correlation coefficient between sRaw responses to cold air repeated within eight weeks was 96%. The authors concluded that sRaw measured by whole body plethysmography was superior in separating asthmatics from healthy control subjects.

**Summary**

Understanding the level of quality that can be achieved within each age group in pediatric testing may influence which tests are most practical to perform in this population. Children can successfully perform pulmonary function testing beginning at age two. Success will be a function of the equipment, test method selected, and most importantly, the ability of the technologist to effectively communicate with the child. In our studies, as compared to an adult population, children with asthma are less likely to achieve ATS standards for spirometry. Lung volumes were the most difficult measurements for us to obtain in the pediatric population with asthma or cystic fibrosis. Airway resistance measurements achieved the highest mean quality score across the age continuum. Airway resistance is performed in a shorter time frame than spirometry, requires less patient cooperation and effort, yields reliable results, has continuity with Raw measurements made in the neonatal period, and offers a cost-effective approach to evidence-based treatment of the child with asthma.

Pulmonary function testing is a valuable tool for the diagnosis and management of chronic respiratory disease. Technology continues to make testing more available and, for some tests, easier to perform. Objective assessment identifies abnormal physiologic processes that result in obstructive or restrictive pulmonary disease and,
Picking Predicteds

by Gregg L. Ruppel, MEd, RRT, RPFT, FAARC, adjunct professor, division of pulmonary, critical care and occupational medicine; director, pulmonary function laboratory; St. Louis University Hospital

Selecting a set of reference equations for use in the pulmonary function or exercise laboratory remains a somewhat controversial topic. There are several reasons for the difficulties encountered when predicted values are selected. Understanding some of the nuances of studies of "normal" lung function can help answer the question of which "predicted" to use.

A practical approach to selecting predicted values involves asking a series of questions:

What equipment and/or techniques were used in the study from which the reference values were derived?

The widespread use of computers in pulmonary function laboratories has reduced the differences between measurements made using volume-displacement versus flow-sensing spirometers. The issue of whether the reference population was studied using equipment similar to that in your laboratory tends to be less important than how the measurements were made. Reference studies performed before 1979 did not have the advantage of the spirometry standardization efforts promulgated by the American Thoracic Society (ATS). Conversely, studies published in the last ten years almost all use the ATS guidelines as minimum requirements for acceptable tests (hence determining which data are included in the "normal" population).

Which populations were included in the study?

The age, sex, and race of the "normal" subjects should reflect a population similar to that tested in your laboratory. Many studies include only a very specific age range (e.g., 15 to 64 years) or include only a single race (e.g., Caucasians). These studies should not be used for individuals (or groups) that fall outside of the limits of the "normals" who were studied. For example, a regression equation derived from normal females aged 15 to 64 should not be extrapolated to predict the expected value in a female who is 66 years old. Some reference studies also used very small numbers (i.e., <100) of apparently healthy subjects. Small sample size does not invalidate their use, but may limit how well the sample represents the population as a whole. Many reference studies sample a group of apparently healthy subjects in a small geographical area. Differences in the local environment (i.e., altitude, level of air pollution) may limit how well the study population compares with those tested in your laboratory.

How large was the sample population and how much variation was observed?

As noted above, sample populations with large numbers of individuals spread across a wide range of ages and heights are preferable to small populations with few subjects at the high and low ends of the distribution. In addition to an adequate number of subjects, the variability of any particular pulmonary function parameter (FVC, FEV1, etc.) should be available from the study data. Most reference studies report variability as either the Standard Error of Estimate (SEE) or Residual Standard Deviation (RSD). If the study data are normally distributed, the lower limit of normal (LLN) can be calculated as the predicted value — 1.645 * SEE.

In order to see how the factors described by these three questions might be used in selecting predicted values, let's compare two studies that might be used to determine reference values for spirometry. Crapo and colleagues published a widely used study in 1981. Hankinson and colleagues recently published spirometry data from the third National Health and Nutrition Examination Survey (NHANES III; 1999).

Equipment and techniques

Crapo used a water-sealed spirometer. NHANES III used a dry rolling-seal spirometer. Both studies adhered to the ATS guidelines for judging the acceptability of spirometry. Crapo's study complied with the original ATS recommendations (1979) while NHANES III complied with the 1987 revisions of the spirometry standards. The NHANES III data were also reanalyzed to follow the latest ATS revisions (1994). (ADVANTAGE: TIE)

Study population

Crapo tested Caucasian subjects who were lifelong nonsmokers. The study was conducted at an altitude of 1400 meters in an area with minimal air pollution (Salt Lake City). NHANES III tested Caucasians, African-Americans, and Mexican-Americans. These subjects were from 81 counties across the United States.
US. Smokers and those with a history of respiratory symptoms (based on strict criteria) were excluded. (ADVANTAGE: NHANES III)

Number of subjects and variability

Crapo tested 125 males ages 15-91, and 126 females ages 15-64. Crapo reported the SEE for spirometric variables. NHANES III tested 7,429 non-smoking subjects ages 8-80. The study included 898 Caucasian males, 1027 African-American males, and 1116 Mexican-American males. Female subjects included 1383 Caucasians, 1481 African-Americans, and 1523 Mexican-Americans. The NHANES III study generated regression equations for estimating the lower limit of normal (LLN) based on normal distributions. (ADVANTAGE: NHANES III)

Establishing new reference sets

This approach to selecting predicteds suggests that NHANES III might be preferred to the Crapo normals based on the population size and diversity. An exception to this conclusion might exist if your laboratory was located at an altitude near 1400 meters and tested only Caucasian subjects.

Pulmonary function laboratories wishing to change reference sets should evaluate the proposed equations by applying them to a sample of healthy subjects. This type of evaluation is fairly easy to do. Twenty to 30 healthy subjects (preferably lifelong nonsmokers) with no history of respiratory symptoms are tested using standardized lab protocols. All of the subjects should have values within normal limits using the current reference equations. Percents of predicted are then recalculated using the same patient data. Most computerized PFT systems allow this to be done simply by switching reference sets. Again, all of the subjects should demonstrate values within the normal limits suggested by the study. Lower limits of normal based on 1.645*SEE or using the 5th percentile are preferable to those using a fixed percentage of the predicted value (i.e., 80%). If a significant number of healthy subjects have values outside the normal limits using the proposed reference set, then it may not accurately represent the population served by the laboratory. Alternatively, the previously used references may have been significantly understimating "normal" lung function.

Laboratories that adopt new reference sets should include a statement detailing the change and its effective date on all reports. Serial studies or trend analyses that use percents of predicted values should also indicate the date that the new reference set was adopted. Including the name (or some notation that can be used to trace the predicteds) on all published reports is a recommended laboratory practice.

Suggested Bibliography


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1. What was the surveyors’ focus during your site visit?____________________________________________
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__________________________________________________________________________________________
__________________________________________________________________________________________

2. What areas were cited as being exemplary?
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3. What suggestions were made by the surveyors?
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4. What changes have you made to improve compliance with the guidelines?
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Additional comments:

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